SEP 2 6 2000

K002030

510(k) Summary of Safety and Effectiveness

Submitter Information:

Invivo Research Inc.
12601 Research Parkway
Orlando, FL 32826
407-275-3220
Contact: Mr. Francis Casey

Product Name:

Proprietary: Omni-Trak 3150/3155 Series Monitor with Anesthetic Agent Monitoring
Common: Anesthetic Gas Analyzer
Classification: Anesthetic Gas Analyzer, enflurane - (73 CBO/21CFR 868.1500 Class II)
Anesthetic Gas Analyzer, halothane - (73 CBO/21CFR 868.1620 Class II)
Oxygen Gas Analyzer - (73 CBO/21CFR 868.1720 Class II)

Predicate Devices:

The predicate device(s) are the Millennia™ Model 3500 Series Anesthetic Gas Monitoring System System (reference 510(k) # K974581), O.D.A.M. Maglife C (510(k) number K972535), Datex AS/3 Anesthesia Agent Monitor (510(k) numbers K832113, K903104, K923276, K932098), the Datascope Multinex Anesthetic Agent Monitor (510(k) numbers K883254, K903104), and the Criticare Poet II Anesthesia Agent Monitor (510(k) numbers K892646, K942737). These predicate devices have the same performance specifications as the Omni-Trak 3150/3155 Series Monitor with Anesthetic Agents Monitor.

Device Description:

The Omni-Trak 3150/3155 Series Monitor with Anesthetic Agents Monitor is a patient monitor which draws a continuous flow of sample gas from the patient's anesthesia breathing circuit. The sample is then drawn through a measurement sample cell where the agent(s) and other patient gas concentrations are measured. Measured values are displayed as numbers and waveforms on the main display of the monitor. The monitor is operated by controls on the front panel of the monitor. The major functional subsystems of the device are the power supply, the pneumatic system, the measurement sample cell, the system electronics and product software. Power is supplied by an AC power cord, or an internal set of batteries. AC power is internally conditioned by the power supply subassembly, which powers the system and charges the internal batteries. The pneumatic system draws sample gas into the device through a moisture collection system. The sample then enters the sample cell, which is a cavity within the optical bench assembly. The sample is then exhausted out the rear of the unit. The sample cell cavity allows

infrared light to be passed through the sample so a detector on the other side of the sample can measure the amount of infrared light absorption. The infrared light source consists of a resistive element which radiates a relatively wide spectrum of infrared light. The amount of transmitted infrared light is measured by an optical detector, and several optical filters are used to determine the identity and concentration of the anesthetic agents, nitrous oxide and carbon dioxide. The oxygen measurements are obtained using a polarographic oxygen cell which also receives sample gas from the sample cell. The electronic system consists of an analog circuit board, and a digital circuit board. These boards are added to the existing standard Omni-Trak 3150/3155 Series Patient Monitoring System. The analog board takes the electrical signals from the sample cell assembly and conditions them so that measurement calculations can be performed. The digital circuit board digitizes the conditioned analog signals and performs measurement calculations. Proprietary software algorithms are used to calculate measured concentrations of anesthetic agents and patient gases in the sample gas.

Intended Uses:

The Invivo Research Inc. Omni-Trak 3150/3155 Series Monitor with Anesthetic Agent monitoring is intended for general hospital or clinical use by medical professionals whenever it is required to monitor concentrations of anesthetic gases within an MRI area. The agents monitored include halothane, enflurane, isoflurane, sevoflurane and desflurane. Additionally, this monitor also monitors end-tidal carbon dioxide, nitrous oxide and oxygen gas concentrations. The need to monitor these anesthetic agents is most commonly encountered in the operating room or MRI area during administration of anesthesia. This device is available for sale only upon the order of a physician or other related licensed medical professional.

Technological Comparison to Predicate Device(s):

The Invivo Research Inc. Omni-Trak 3150/3155 Series Monitor with Anesthetic Agent monitor uses a polychromatic non-dispersive infrared light (NDIR) system to identify and measure the anesthetic gases and carbon dioxide. This technology is identical to the other cited predicate devices listed above.

Summary of Performance Testing:

The Invivo Research Inc. Omni-Trak 3150/3155 Series Monitor with Anesthetic Agent monitor conforms with national and available international product safety standards for electrical, electromagnetic compatibility, and anesthetic agent monitoring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

Mr. Francis Casey
Invivo Research, Inc.
12601 Research Parkway
Orlando, FL 32826

Re: K002030
Omni-Trak™ Model 3150/3155A Series Anesthetic Gas Monitoring System
Regulatory Class: II (two)
Product Code: 73 MWI
Dated: June 30, 2000
Received: July 3, 2000

Dear Mr. Casey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002030

Intended Uses

The Invivo Research Inc. Omni-Trak 3150/3155 Series Monitoring System is a device comprised of two separate monitors: the 3150 Monitor, which operates as the base monitor, and the 3155 Monitor, which operates as a Remote Display monitor. The 3150 and 3155 Monitors communicate through a bi-directional radio-link which operates within the MRI area.. Both monitors display the patient information, and must be used together for the system to operate. A warning message is displayed if the radio-link is broken.

The Invivo Research Inc. Omni-Trak 3150/3155 Series Monitor with Anesthetic Agent monitoring is intended for general hospital or clinical use within a magnetic resonance imaging (MRI) area by medical professionals whenever it is required to monitor concentrations of anesthetic gases. The agents monitored include halothane, enflurane, isoflurane, sevoflurane and desflurane. Additionally, this monitor also monitors end-tidal carbon dioxide, nitrous oxide and oxygen gas concentrations. The need to monitor these anesthetic agents is most commonly encountered in the operating room or MRI area during administration of anesthesia. This device is available for sale only upon the order of a physician or other related licensed medical professional.

for

Division of Cardiovascular & Respiratory Devices
510(k) Number K002030

Prescription Use ✓